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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed

Section *Animal Nutrition*

09 - 10 February 2021

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SUMMARY REPORT

As mentioned in the invitation to the meeting sent out on 25 January 2021, the meeting was **held via videoconference** due to the situation derived from the COVID-19 pandemic.

The invitation provided relevant information concerning the modalities of the meeting and referred to the use of the written procedure for the delivery of the Committee opinions on the draft implementing acts under Section B of the meeting's agenda.

During the meeting, the following introductory statements were made by a representative of the Commission:

- The confidentiality obligations required by Article 13 of the Standard Rules of Procedure for Committees and referred to in the invitation to the meeting, were recalled.
- The modalities for the delivery of the Committee opinions on the draft acts under Section B of the meeting's agenda by written procedure, were explained.

Section A Information and/or discussion

A.01 Feed Additives - Applications under Regulation (EC) No 1831/2003 Art. 4, 14 or 13

Documents were sent to the Member States.

A.02 Feed Additives - Applications under Regulation (EC) No 1831/2003 Art. 9

A.02.01 Safety of 31 flavouring compounds belonging to different chemical groups when used as feed additives for all animal species

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.02 L-threonine produced by *Escherichia coli* CGMCC 13325 as a feed additive for all animal species (FAD-2020-0017) - Annex entry

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and a draft Annex entry was presented. A draft authorisation Implementing Regulation will be proposed for one of the next Committee meetings.

A.02.03 Zinc chelate of hydroxy analogue of methionine for all animal species (FAD-2019-0034) - Annex entry

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and a draft Annex entry was presented. A draft authorisation Implementing Regulation will be proposed for one of the next Committee meetings.

A.02.04 6-phytase for pigs other than sows, sows, poultry for fattening and breeding other than turkeys for fattening, poultry for laying and turkeys (FAD-2019-0027) - Annex entry

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and a draft Annex entry was presented. A draft authorisation Implementing Regulation will be proposed for one of the next Committee meetings.

A.02.05 Endo-1,4-beta-xylanase and endo-1,4-beta-glucanase for piglets (weaned), laying hens, chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, turkeys for breeding purposes, ducks for fattening, all minor avian species for laying, minor poultry species for fattening (other than ducks for fattening) and ornamental birds (FAD-2018-0022) - Annex entry

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and a draft Annex entry was presented. A draft authorisation Implementing Regulation will be proposed for one of the next Committee meetings.

A.02.06 Safety and efficacy of STENOROL® (halofuginone hydrobromide) as a feed additive for chickens for fattening and turkeys

A discussion was held on the proposed roadmap of the supplementary studies to be submitted by the applicant. The Member States agreed on it and requested to have a two-step opinion: a first opinion on general issues and a second one later, on target animal species.

A.03 Information point on EU-UK readiness and preparedness as from 1 January 2021

The Member States were invited before the meeting to submit in written form any questions they had relating to actions needed to implement the EU-UK Withdrawal Agreement. The questions submitted were read and answered. The Commission's representative updated the Member States on the state of negotiations and invited the Member States to present any questions that may arise at the next Committee meeting, where the information point will be put again on the agenda.

A.04 Feed marketing Regulation (EC) No 767/2009

A.04.01 Revision of Regulation (EU) No 68/2013 on the Catalogue of feed materials

The Committee discussed a new version of the draft to revise the Catalogue of feed materials, in particular the hemp entries and algae meal. Progress was made on how to prohibit the placing on the market of non-eligible hemp-derived products and the iodine content in algae meal. Discussions were launched to integrate provisions from the ABP and TSE Regulations into specific entries in chapters 8-10 of the Catalogue. Work on the draft will continue at the next Committee meeting.

A.04.02 Revision of Annex III

This item was discussed in the margins of item A.04.01.

A.04.03 State of play on applications for feed for particular nutritional purposes

Nothing to update.

A.04.04 Discussion of borderline products, including arbitrary entries in the Register of feed materials

Polyacrylamide powder to be added to water to produce a gel for insects

The discussion from the last meeting was continued. The Committee considered the conditions to classify polyacrylamide powder added to water for insects neither fulfilled for processing aids, nor for feed materials. Based on the information available, the most appropriate classification seems to be a zootechnical feed additive in the functional group physiological condition stabilisers.

Tracers

The Committee discussed the status of tracers in the Feed legislation. They do not fall under the definitions of "Carrier" or "Processing aids" and cover a broad range of products. Tracers are characterised by their function, such as unique identification of feed additives & premixtures in compound feed or the validation of feed production processes. This function can be achieved by feed materials or feed additives. A general classification of tracers as feed materials is not appropriate.

A.04.05 Labelling of feed for rabbit and koi carp food

A discussion took place based on a document received from the pet food industry. The Committee will come back on the issue after the Member States delegations had time to examine it.

A.05 Insects for feed:

- **Feeding of live insects**

With reference to Article 15(6) of Regulation (EC) No 178/2002, a Commission representative clarified that the placing on the market of live insects for feed must comply with "specific provisions of national law governing feed safety of the Member State in whose territory the feed is in circulation". This applies to live insects as feed for pets but also for food-producing animals. He stressed that the placing on the market of live insects as feed materials is limited to the territory of the respective Member States and that intra-EU trade must be pre-notified to the Competent Authority of the receiving Member State.

- **IPIFF's Guide on Good Hygiene Practices for producers of insects as food & feed**

The revised version of the Guide on Good Hygiene Practices for producers of insects as food & feed from IPIFF was distributed to the Member States delegations. The examination in the area of food hygiene has already started. The delegations are invited to send their comments on the Guide by 22 March 2021.

A.06 Medicated Feed Regulation (EU) 2019/4 – update

The Commission's representative reminded the Member States about the application date of the new medicated feed Regulation in less than a year, and highlighted in particular the provisions about penalties as referred to in Article 22 thereof. He informed the Committee that the scientific risk assessment concerning maximum levels

of cross-contamination carried out by EFSA, as referred to in Article 7(3) of the Regulation, is scheduled for September 2021.

A.07 Restriction of flavourings to marine animals

A document was presented, including information on the use of flavourings for fish in recirculation aquaculture systems and the possible environmental impact of those flavourings in such systems.

A.08 RASFF

The Commission's representative informed the Committee on the RASFF notifications related to undesirable substances in animal feed, issued since the meeting of the Committee in December 2020.

The notifications related to a too high level/content of:

- aflatoxins in pet food products from US;

- aflatoxin B1 (220 µg/kg) in groundnuts for birds from Argentina;

- mercury (2.9 mg/kg) in yeast from Brazil;

- ragweed seeds (329 mg)/kg in buckwheat from Poland;

- ergot sclerotia (4948 and 1069 mg/kg) in rye from Germany;

- matrine (0.13 mg/kg) in organic feed for dairy cattly from the Netherlands.

Furthermore, an update on the outcome of the investigations related to the finding in Ireland of zilpaterol in sugar cane molasses from South-Africa has been provided. The contamination was traced back to a sugar mill in South Africa that operates with only one blend tank at its feed site. This tank is used for blending standardized molasses, containing zilpaterol, for the local South African market. The blend tank was not sufficiently cleaned for use of production of sugar cane molasses for export and this resulted in a cross-contamination with zilpaterol of sugar cane molasses exported to Ireland. The necessary measures have been put in place to prevent avoid re-occurrence of such a cross-contamination.

A.09 Undesirable substances

The Committee was informed that the targeted stakeholder consultation on envisaged provisions on deoxynivalenol, T-2 and HT-2 toxin, zearalenone, fumonisins and ochratoxin was launched on 8 February 2021 with deadline 5 March 2021. A stakeholder forum providing the opportunity to stakeholder organisations to present their positions is foreseen on 9 March 2021. The joint letter from the EU feed and food chain as regards the management of mycotoxins in the feed and food chain and of the reply given by the Commission was mentioned.

The Commission's representative informed the Committee that a meeting of the Working Group “Undesirable substances” is scheduled on 19 February to discuss the following topics:

- presentation of EFSA opinion on nitrates and nitrites in feed and discussion on regulatory follow-up;
- lead in game meat for use in pet food;
- tetrahydrocannabinol (THC) in feed materials derived from hemp;

- dioxins and PCBs;
- ergot sclerotia;
- ergot alkaloids;
- lead in humic acid;
- arsenic in fish meal;
- tropane alkaloids and pyrrolizidine alkaloids;
- per fluor alkylated substances (PFAS). Follow up to EFSA opinion;
- quinolizidine alkaloids. Follow up to EFSA opinion.

A.10 Methods of analysis

The Commission's representative informed the Committee that a working group "Methods of Analysis" is foreseen to be held on 24 February 2021 to continue the discussion on outstanding issues in particular on:

- the sample size for visual inspection (macroscopic analysis);

- reference to EN/ISO standards for methods of analysis for analytes currently not provided for in the Annex to Regulation (EC) 152/2009;

- sampling provisions for feed traded by distance selling (e-commerce).

As regards the sample size for visual inspection (macroscopic analysis) several delegations stressed that the burden of analysis should not be significantly increased compared to the current practice applied in many Member States, while acknowledging that it might be appropriate to make improvements to increase the accuracy.

Several delegations highlighted also the need to introduce without delay specific provisions for sampling of feed traded by distance selling (e-commerce).

Section B Drafts presented for discussion prior to an opinion by written procedure

The documents concerning the items under this section were communicated to the Committee members in advance of the meeting for possible comments.
During the meeting, an exchange of views took place on each of the draft measures referred to under items B.01, B.02, B.03, B.05, B.06, B.07 and B.08 in order to reach an agreement on the content of the respective documents.
After the meeting, a final version of the documents resulting from the discussions held during the meeting was sent to the Committee members for possible rectification or editorial comments, with a deadline for reply set on 15 February 2021. The Committee's opinion on the draft act referred to under item B.04 of the meeting's agenda will be sought at a later stage, after completion of preliminary internal procedural requirements.
In accordance with Article 3(5) of Regulation (EU) No 182/2011, the **written procedure** for the delivery of the Committee opinion on the seven draft Implementing Regulations concerned was launched on 17 February 2021 with a deadline set on 24 February 2021.
Member States representatives were informed on the outcome of the written procedure by a note sent on 1 March 2021. The Committee opinion delivered on each draft measure is mentioned below in relation to items B.01, B.02, B.03, B.05, B.06, B.07 and B.08.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 371/2011 as regards the name of the holder of the authorisation of dimethylglycine sodium salt as feed additive

The draft refers to the change of the name of the holder of the authorisation of dimethylglycine sodium salt as feed additive.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 887/2011 and Implementing Regulation (EU) 2017/961 as regards the name of the holder of the authorisation of *Enterococcus faecium* CECT 4515 as a feed additive and amending Implementing Regulation (EU) 2020/1395 as regards the name of the holder of the authorisation of *Bacillus amyloliquefaciens* CECT 5940 as a feed additive

The draft refers to the change of the name of the holder of the authorisation of *Enterococcus faecium* CECT 4515 and of *Bacillus amyloliquefaciens* CECT 5940 as feed additives.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation on the status of certain products as feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council and on the withdrawal from the market of certain feed additives

The draft refers to the withdrawal from the market of feed additives for which no application for (re-)authorisation was submitted (or for which the application was withdrawn) in accordance with Article 10(2) of Regulation (EC) No 1831/2003. It also determines whether certain products are or are not feed additives within the scope of Regulation (EC) No 1831/2003.

The Committee was informed that the draft measure has been notified under the SPS Agreement and that no comments were received.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of vitamin B12 in the form of cyanocobalamin produced by *Ensifer* spp. as a feed additive

The item was not discussed.

Vote Postponed

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of essential oil from *Origanum vulgare* L subsp. *hirtum* (Link) letsw. Var. Vulkan (DOS 00001) as a feed additive for all animal species

The draft refers to the authorisation of one botanical flavouring produced from *Origanum vulgare* L subsp. *hirtum* (Link) letsw. Var. Vulkan (DOS 00001) as a feed additive for all animal species.

Declaration on the authorisation of essential oil from *Origanum vulgare* L subsp. *hirtum* (Link) letsw. Var. Vulkan (DOS 00001) as a feed additive for all animal species:

« The Committee highlighted that the draft Implementing Regulation concerns the authorisation of an additive belonging to the category 'sensory additives' and to the functional group 'flavouring compounds'. Accordingly, it was reminded that any use of the additive, and any related presentation thereof, which would aim at producing other effects (such as zootechnical effects) would constitute an infringement of the authorising act and of Regulation (EC) No 1831/2003, irrespectively of the compliance with the other provisions laid down in the authorising act, such as the set maximum content of the additive in feed. »

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of L-histidine monohydrochloride monohydrate produced by *Escherichia coli* KCCM 80212 as a feed additive for all animal species

The draft refers to the authorisation of an amino acid as feed additive.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of technically pure L-lysine monohydrochloride and liquid L-lysine base produced by *Corynebacterium casei* KCCM 80190 or *Corynebacterium glutamicum* KCCM 80216 or *Corynebacterium glutamicum* KCTC 12307BP as feed additives for all animal species

The draft refers to the authorisation of two amino acids as feed additives.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.358 as a feed additive for all animal species

The draft refers to the authorisation of an amino acid as feed additive.

Vote taken: Favourable opinion.

M.01 Safety of potassium diformate (FormiTM LHS) as a feed additive for sows, from ADDCON EUROPE GmbH

A discussion was held. A draft Implementing Regulation will be presented at a future Committee meeting.

M.02 Tolerances of feed additives in premixtures

Further to a question raised by a Member State delegation, a Commission's representative indicated the following:

It is clear that the application of analytical tolerances (measurement uncertainty) based on the analytical method for the respective substance is not questioned as regards additives in premixtures.

As regards the application of technical tolerances (in relation to the manufacturing of the product), due to the current absence of EU rules allowing such tolerances for additives in premixtures, it is up to the competent authority of the Member State, where the premixture is placed on the market, what tolerance it applies, insofar the general rules laid down in EU legislation, both concerning safety and labelling, are complied with. Thus, the national authorities would not be obliged to accept technical tolerances established by the national rules of another Member States. It should be mentioned that the Commission does not have an overview of the tolerances applied by the different Member States.

Considering that the setting of tolerances is also being considered in the context of the preparation of future EU legislation on feed additives/premixtures, the following pragmatic approach could be followed pending the finalisation of the revision of the feed additives Regulation: the technical tolerances already established for feed materials and compound feed in Part B of Annex IV of Regulation (EC) No 767/2009 could be taken as reference values.

M.03 Impact assessment of Feed Additives Regulation

The Commission's representative informed the Committee about the different consultations envisaged in the impact assessment in view of the revision of the Feed Additives Regulation. The consultation strategy was uploaded in CIRCABC.